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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/873,505	06/04/2001	Hongjie Cao	1928.PC	4692
35157 7590 12/25/2007 NATIONAL STARCH AND CHEMICAL COMPANY P.O. BOX 6500 BRIDGEWATER, NJ 08807-3300				
EXAMINER				
YU, GINA C				
ART UNIT		PAPER NUMBER		
1617				
NOTIFICATION DATE		DELIVERY MODE		
12/25/2007		ELECTRONIC		

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte HONGJIE CAO and GARY T. MARTINO

Appeal 2007-1645
Application 09/873,505
Technology Center 1600

Decided: December 20, 2007

Before DEMETRA J. MILLS, NANCY J. LINCK, and
RICHARD M. LEBOVITZ, *Administrative Patent Judges*.

LINCK, *Administrative Patent Judge*.

DECISION ON APPEAL

This is a 35 U.S.C. § 134 appeal in the above-referenced case.¹
We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

The field of the invention is aqueous personal care and cosmetic
formulations containing starch-encapsulated hydrophobic compounds

¹ The application was filed June 4, 2001. The real party in interest is National Starch and Chemical Investment Holding Corporation (Substitute Appeal Brief Under 37 C.F.R. § 41.37 (hereafter "App. Br.") 1).

(Specification (hereafter "Spec." 1)). The claimed subject matter is reflected in the following representative claims (disputed language italicized):

32. A stable, aqueous personal care or cosmetic formulation comprising:
- a) a cationic starch-encapsulated hydrophobic material;
 - b) water,
- wherein said starch-encapsulated hydrophobic material is *essentially non-separable* in said personal care or cosmetic aqueous formulation and the formulation is surfactant-free.

In their "Background of the Invention," Appellants note that a number of prior art references, including Eskins et al., U.S. Patent No. 5,676,994 (Oct. 14, 1997²) "disclose the preparation of non-separable starch-oil compositions formed by jet-cooking a mixture of starch and other materials" (Spec. 1). Referring back to these references, Appellants state:

Surprisingly it has been found that these stable water insoluble starch-oil compositions are suitable for use in aqueous-based personal care and cosmetic formulations. In such formulations, the starch-encapsulated hydrophobic compounds may provide additional benefits including a delivery system, a time release mechanism, a thickening mechanism, protection of the hydrophobic compound during processing and storage, retention on hair and skin, and a formulation without a greasy feel, and a formulation without a surfactant or emulsifying agent. Additionally, the starch encapsulant provides a smooth after-feel.

(*Id.*)

The Examiner has rejected claims 26-48 under 35 U.S.C. § 103(a) as follows:

² The dates given for patents are issue dates.

I. Claims 32-35, 39-42 and 46-48 are rejected over Eskins; Van Soest et al., U.S. Patent No. 6,340,527 B1 (Jan. 22, 2002); Fletcher et al., U.S. Patent No. 6,261,543 B1 (Jul. 17, 2001); and Robert L. Goldemberg, 159 Drug & Cosmetic Industry 50-53 (Society of Cosmetic Chemists seminar) (New York 1996). (This combination of references is hereafter referred to as "the primary combination of references.")

II. Claims 26-28 are rejected over the primary combination of references and additionally Macaulay, U.S. Patent No. 6,362,146 B1 (Mar. 26, 2002).

III. Claims 29-31, 36-38 and 43-45 are rejected over the primary combination of references, and additionally Macaulay and Laurence W. Ashley, *Sunburn and Sunscreen Preparations*, 3 Poucher's Perfumes, Cosmetics and Soaps 431-37 (9th ed. 1993).

OBVIOUSNESS UNDER § 103(a)

The § 103(a) Issues

With respect to each of the three grounds of rejection, Appellants contend there would have been no motivation to combine the cited references (App. Br. 12, 14, 15). Appellants further contend "none of the cited references, alone or in combination, teach[es] or suggest[s] . . . cationic-starch encapsulated hydrophobic material that is non-separable in a surfactant-free, aqueous formulation" (*see id.*). According to Appellants, this means their "encapsulant with the active ingredient therein remain[s] intact in the aqueous formulation (i.e., does not disperse out in the water)" (App. Br. 2 (citing Spec. 2, ll. 6-8 & 12-18)).

With respect to Appellants' first contention regarding motivation to combine the cited references, the Examiner found (1) Eskins teaches the advantages of using modified starch and each of Van Soest, Fletcher and Goldemberg teaches the advantages of using modified cationic starch (Examiner's Answer (mailed Dec. 4, 2006) (hereafter "Ans.") 8, 9); (2) Eskins and Van Soest teach their inventions are useful as carriers or vehicles for cosmetic formulations and Macaulay teaches compositions containing sunscreen (*id.* at 9-10); and (3) Ashley teaches examples of the conventional sunscreen formulations containing water (*id.* at 6).

With respect to Appellants' contention that their claimed formulation does not "disperse out in the water," the Examiner responds that Appellants teach otherwise throughout their Specification, and, in any case, Eskins discloses "droplets of oil that are entrapped within a starch matrix" and thus are "equivalent to encapsulated oils," as claimed by Appellants (Ans. 8). According to the Examiner, the only difference between Eskins' entrapped oil droplets and Appellants' is in their size (*id.* at 7-8).

Given these divergent positions, we frame the § 103(a) issues as follows:

Would the skilled artisan have been motivated to combine the cited references at the time the claimed invention was made, and, if so, would such a combination have taught or suggested a non-separable, cationic starch-encapsulated hydrophobic material, as recited in claim 32?

Findings of Fact Relating to Obviousness

1. The claims, as originally filed, were limited to "essentially non-separable" starch-encapsulated hydrophobic compounds but were not limited to cationic starch-encapsulated compounds or to those containing a sunscreen (*see* claim 1 (Spec. 17)), limitations later added by amendment.

2. Thus the originally filed claims do not suggest the language "essentially non-separable" was intended to limit the pending claims to a specific embodiment.

3. With this understanding, we give the phrase "non-separable" its broadest reasonable interpretation, when read in light of the Specification, and find it means a "starch-encapsulated hydrophobic compound" that "remains intact in an aqueous solution, and separates only with the addition of mechanical energy" (Spec. 2) and is not "destroyed in the aqueous environment" (*id.*).

4. However, the phrase "non-separable" does not mean the encapsulated compound cannot be dispersed in water (*see* Appellants' "Characteristics of Starch-Lipid Encapsulations," for example, Spec. 8, ll. 8-9 ("Dispersion appearance of the starch-hydrophobe encapsulations varies with different starch base"); *see also* Spec. 8, ll. 15-16 & 18-20).

5. At the time their application was filed, Appellants "[s]urprisingly" found that Eskins' "stable water insoluble starch-oil compositions" were "suitable for use in aqueous-based personal care and cosmetic formulations" (Spec. 1), suggesting they understood their contribution to be a new use.

6. Appellants noted the Eskins' compositions "may provide additional benefits including a delivery system, a time release mechanism, a thickening

mechanism, protection of the hydrophobic compound during processing and storage, retention on hair and skin, and a formulation without a greasy feel, and a formulation without a surfactant or emulsifying agent" and a smooth after-feel" (Spec. 1).

7. As admitted by Appellants, "protecting sensitive ingredients" through the "use of modified starches as encapsulating agents" was known in the art at the time the application was filed (Spec. 1, ll. 18-20).

8. Likewise, as admitted by Appellants, their jet-cooking process was also known and used by Eskins to prepare their compositions (Spec. 3, ll. 18-25).

9. Repeatedly, Appellants have characterized their starch-lipid encapsulations as "dispersions" (*see, e.g.*, Spec. 8, 9, 14).

10. Eskins discloses a "stable and non-separable composition comprised of starch and oil . . . prepared in the absence of external emulsifying or dispersing agents" (Abstract), in the form of an aqueous dispersion and a dried powder (col. 12, ll. 28-29).

11. Eskins discloses prior art modified starch and notes the "modified starch does not have the sticky, gummy properties of unmodified starch and also functions as an emulsion stabilizer" (col. 3, ll. 55-63).

12. Eskins teaches that modified starches may be used to prepare their stable, non-separable compositions "if certain properties are desired that are not obtainable with unmodified starches" (col. 6, ll. 32-34).

13. Eskins discloses additional agents can be "entrapped for prolonged periods of time within the substantially dry starch matrix," i.e., one typically having 5-12% moisture (col. 11, ll. 18-19), and will be

"immediately released when the starch matrix is either scratched or broken" (col. 7, ll. 31-35).

14. Eskins' "cooking is preferably carried out with an excess-steam jet cooker" (col. 8, ll. 16-17), "which not only emulsifies the oil in the aqueous starch solution by also provides an emulsion of starch, oil and water that will not phase separate, even after prolonged standing" (col. 8, ll. 31-34).

15. Eskins uses the term "emulsion" to refer to their "micron-sized droplets of oil uniformly entrapped within a starch or starch-water matrix" (col. 8, ll. 34-36), thereby distinguishing their compositions from "encapsulated" prior art oils in which "relatively large drops of oil are encased with a protective layer of starch" (col. 8, ll. 51-53).

16. Eskins theorizes "the helical starch polymer formed from repeating glucose units has its hydrogen atoms located inside the helix, thus giving the helical cavity a hydrophobic surface necessary for compatibility with guest molecules, such as a fat or oil" (col. 10, ll. 1-5).

17. Eskins' compositions are disclosed as "useful as carriers or vehicles in pharmaceutical, cosmetic and personal care product formulations," including "sun tan lotions and creams" (col. 11, ll. 60-65).

18. Eskins does not teach and would not have suggested their "micron-sized droplets of oil uniformly entrapped within a starch or starch-water matrix" would not have remained entrapped when exposed to water (see FF 5-6, 8-18).

19. Thus, Eskins teaches all the limitations of claim 32, except cationic modification of the starch (FF 1-18).

20. There was a recognized need for stability in the prior art (*see, e.g., Fletcher, col. 1, l. 38 to col. 2, l. 33*).

21. Fletcher discloses antiperspirant emulsions with "excellent phase stability," obtained with a "cationic modified starch" (Abstract).

22. Van Soest discloses a "process for the preparation of microparticles which contain an active ingredient, such as paramagnetic particles, in a starch solution, cross-linking the starch with a phosphate and then emulsifying the starch . . . in a hydrophobic medium" (col. 1, ll. 7-12).

23. Van Soest's "active ingredient is encapsulated" and "released only under specific chosen conditions or after a relatively long period" (col. 1, ll. 30-34).

24. According to Van Soest, an "important constituent of the microparticles is starch, which has the advantage of being able to encase a multiplicity of active ingredients" (col. 1, ll. 52-54).

25. Van Soest characterizes "native starch and fractions and derivatives thereof" as suitable and "granular starch, which can be native or modified native starch and is not water-soluble," as preferred (col. 1, ll. 55-58).

26. Granular starch is "considered chemically or physically modified starch" (Van Soest, col. 1, l. 67 to col. 2, l. 1).

27. "Suitable derivatives" taught by Van Soest include "cationic starch" (col. 2, ll. 3-5).

28. The advantages of using granular starches are, *inter alia*, the ability to use a higher starch concentration, or one with a higher molecular weight, permitting the preparation of a shell with a "higher network density,

which may be advantageous for the release properties" (Van Soest, col. 2, ll.12-16).

29. Goldemberg discloses "the entrapment and stabilization of free radical scavengers via so-called 'Glycospheres' . . . which contain a cationic polysaccharide core (modified starch)" (Goldemberg 2 (para. 6)).

30. Thus, numerous prior art references taught or would have suggested the advantages of cationic modified starch in encapsulating or entrapping oil droplets and other active ingredients (FF 21-29).

31. Macaulay discloses "encapsulated sunscreen" (Abstract), just as does Eskins (FF 17).

32. Ashley discloses "the most popular formulation type for sunscreen products are the emulsions" which may be "oil-in-water, water-in-oil, or more complex in nature" (Ashley 431).

33. Formulations, such as those claimed and taught in the prior art, contain varying levels of water (*see, e.g.*, Ashley 434-36; FF 10, 13, 21), and optimization of the moisture level would have been well within the skill in the art (*see* Ans. 10).

34. One skilled in the art would have been motivated to combine the cited prior art based on the advantages taught by each of the references (FF 5-33) and would have had a reasonable likelihood of success in obtaining a composition according to claim 32.

Discussion of the § 103(a) Issue

Based on our findings and those of the Examiner, we find the skilled artisan would have been motivated to combine the cited references at the

time the claimed invention was made in order to address known challenges with prior art compositions, such as stability and encapsulation of sunscreen (FF 34). "When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103." *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1742 (2007).

We further find such a combination of references would have taught or suggested a non-separable, cationic starch-encapsulated hydrophobic material, as recited in claim 32 (FF 1-34). Accordingly, we conclude the composition of claim 32 would have been obvious to one of ordinary skill in the art at the time the invention was made (*id.*). Claims 33-35, 39-42 and 46-48 were not argued separately and thus fall with claim 32. *See* 37 C.F.R. § 41.37(c)(1)(vii) (2006).

With respect to the other § 103(a) grounds of rejection (*see supra* p. 3), again Appellants' arguments are based upon the limitation found in claim 32, i.e., "wherein said starch-encapsulated hydrophobic material is essentially non-separable" (App. Br. 10-12, 14, 15; Reply Br. 2-3). Accordingly, we affirm these § 103(a) rejections for the reason given above.

We adopt the Examiner's response as our own to any additional arguments not expressly discussed above (Ans. 6-10).

CONCLUSION

We affirm the § 103(a) rejections of claims 26-48 for the reasons given above.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv)(2006).

AFFIRMED

Ssc:

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